



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of PANVAC™ and Tumor Associated Antigens as Colorectal Cancer Vaccine.

AGENCY: National Institutes of Health, Public Health Service, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Bavarian Nordic Immunotherapeutics (“BNIT”) located in Mountain View, CA, USA.

Intellectual Property:

Group I—Exclusive Licensed Patent Rights

1. U.S. Patent Application No. 60/061,589 filed October 10, 1997 as well as all issued and pending foreign counterparts [HHS Ref. No. E-099-1996/0-US-01];
2. PCT Patent Application No. PCT/US1998/19794 filed September 22, 1998 as well as all issued and pending foreign counterparts [HHS Ref. No. E-099-1996/0-PCT-02];
3. U.S. Patent No. 6,756,038 issued June, 29 2004 as well as issued and pending foreign counterparts [HHS Ref. No. E-099-1996/0-US-07];

4. U.S. Patent No. 7,723,096 issued May 25, 2010 as well as continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-0991996/0-US-08];
5. European Patent No. IOI7810 [HHS Ref. No. E-099-1996/0-EP-05], and all European contracting states in which this patent is validated;
6. European Patent Application No. 04011673.3 (now EP Patent No. 1447414) [HHS Ref. No. E-099-1996/0-EP-17], and all European contracting states in which this patent is validated, Japan Patent Application No. 2000-516030 (now JP Patent No. 4291508) [HHS Ref. No. E-099-1996/0-JP-06], and all continuations and divisional applications claiming priority to this application;
7. Australia Patent No. 745863 [HHS Ref. No. E-099-1996/0-AU-03], and all continuations and divisional applications claiming priority to this application;
8. Canada Patent No. 2308127 [HHS Ref. No. E-099-1996/0-CA-04], and all continuations and divisional applications claiming priority to this application;
9. PCT Patent Application No. PCT/US1992/03843 filed May 6, 1992 as well all issued and pending foreign counterparts [HHS Ref. No. E-200-1990/2-PCT-01];
10. U.S. Patent No. 5,698,530 issued December 6, 1997 as well as issued and pending foreign counterparts [HHS Ref. No. E-200-1990/1-US-02];
11. Australian Patent No. 674492 issued April 22, 1997 [HHS Ref. No. E- 200-1990/2-AU-02]; Europe Patent No. 0584266 issued September 3, 2003 [HHS Ref. No. E-200-1990/2-EP-04]; Japan Patent No. 3399943 issued February 21, 2003 [HHS Ref. No. E-200-1990/2-JP-05]; and Canada Patent No. 2102623 issued April 22, 2003 [HHS Ref. No. E-200-1990/2-CA-03];
12. U.S. Patent No. 6,001,349 issued 14 Dec. 1999 as well as issued and pending foreign counterparts [HHS Ref. No. E-200-1990/3-US-01];

13. U.S. Patent Application No. 60/519,354 filed November 12, 2003 as well as all issued and pending foreign counterparts [HHS Ref. No. E-087-2005/0-US-01];
14. U.S. Patent Application No. 10/579,025 filed May 11, 2006 as well as all continuation and divisional applications, and issued and pending foreign counterparts [E-0872005/0-US-03];
15. U.S. Patent Application No. 60/519,427 filed November 12, 2003 as well as all issued and pending foreign counterparts [HHS Ref. No. E-088-2005/0-US-01];
16. U.S. Patent Application No. 10/579,007 filed May 11, 2006 as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-088-2005/0-US-03];
17. U.S. Patent Application No. 60/038,253 filed February 24, 1997 as well as all issued and pending foreign counterparts [HHS Ref. No. E-154-1998/0-US-01];
18. PCT Patent Application No. PCT/US1998/03693 filed February 24, 1998 as well all issued and pending foreign counterparts [HHS Ref. No. E-154-1998/0-PCT-02];
19. U.S. Patent No. 7,118,738 issued October 10, 2006 as well as all continuations and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-154-1998/0-US-07];
20. PCT Patent Application No. PCT/US1995/12638 filed October 2, 1995 as well all issued and pending foreign counterparts [HHS Ref. No. E-259-1994/2-PCT-01];
21. PCT Patent Application No. PCT/US1997/12203 filed July 15, 1997 as well all issued and pending foreign counterparts [HHS Ref. No. E-259-1994/3-PCT-02];
22. U.S. Patent Application No. 08/686,280 filed July 25, 1996 as well as all issued and pending foreign counterparts [HHS Ref. No. E-259-1994/3-US-01];
23. U.S. Patent No. 7,410,644 issued August 12, 2008 as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-259-1994/3-US-08];

24. PCT Patent Application No. PCT/US1995/12624 filed October 2, 1995 as well all issued and pending foreign counterparts [HHS Ref. No. E-260-1994/2-PCT-01];
25. U.S. Patent Nos. 6,893,869, 6,548,068 and 6,045,802 issued May 17, 2005, April 15, 2003 and April 4, 2000 respectively, as well as issued and pending foreign counterparts [HHS Ref. Nos. E-260-1994/1-US-03, US-02, US-01]; U.S. Patent No. 7,368,116 issued May 6, 2008 and U.S. Patent Application No. 12/112,819, as well as all continuation and divisional applications [HHS Ref. Nos. E-260-1994/1-US-04 and US-05];
26. Europe Patent Application No. 00102998.2 filed October 2, 1995, Europe Patent No. 0784483 issued November 29, 2001, Europe Patent Application No. 09013495.8 filed October 26, 2009, as well as all continuation, and divisional applications [HHS Ref. Nos. E-260-1994/2-EP-15, EP-16 and EP-27]; Japan Patent Application No. 512100/96 filed October 2, 1995; Japan Patent No. 4078319 issued February 8, 2008 [HHS Ref. No. E-260-1994/2-JP-25]; and Japan Patent No. 4160612 issued July 25, 2008, as well as all continuation and divisional applications; [HHS Ref. No. E-260-1994/2-JP-21, JP-25 and JP-26]; Australia Patent No. 688606 issued July 2, 1998 [HHS Ref. No. E-260-1994/2-AU-11]; Canada Patent No. 2201587 issued June 25, 2002 [HHS Ref. No. E-260-1994/2-CA-12];
27. U.S. Patent Application No. 60/211,717 filed June 15, 2000 as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-187-2000/0-US-01];
28. PCT Patent Application No. PCT/US2001/19201 filed June 15, 2001 as well all issued and pending foreign counterparts [HHS Ref. No. E-187-2000/0-PCT-02];
29. Canada Patent Application No. 2,412,050 filed June 15, 2001 [HHS Ref. No. E-187-2000/0-CA-05]; Australia Patent No. 2001268452 issued November 30, 2006 [HHS Ref. No. E-187-2000/0-AU-06]; Japan Patent Application No. 2002-510097 filed

June 15, 2001 [HHS Ref. No. E-187-2000/0-JP-07]; Hong Kong Patent Application No. 03105975.5 filed June 15, 2001 [HHS Ref. No. E-187-2000/0-HK-08]; as well as all continuation and divisional applications;

30. U.S. Patent Application No. 60/776,506 filed February 24, 2006 as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-104-2006/0-US-01];
31. PCT Patent Application No. PCT/US2007/004603 filed February 27, 2007 as well all issued and pending foreign counterparts [HHS Ref. No. E-104-2006/0-PCT-02];
32. U.S. Patent Application No. 12/ 280,534 filed February 21, 2007, [HHS Ref. No. E-104-2006/0-US-06]; Australia Patent Application No. 2007221255 filed February 21, 2007 [HHS Ref. No. E-104-2006/0-AU-03]; Europe Patent Application No. 07751371.1 filed February 21, 2007, [HHS Ref. No. E-104-2006/0-US-06]; filed February 21, 2007, [HHS Ref. No. E-104-2006/0-EP-05]; Canada Patent Application No. 2642994 filed February 21, 2007 [HHS Ref. No. E-104-2006/0-CA-04]; as well as all continuation and divisional and applications
33. U.S. Patent Application No. 60/904,236 filed February 28, 2007 as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-074-2007/0-US-01];
34. PCT Patent Application No. PCT/US2008/055185 filed February 28, 2008 as well all issued and pending foreign counterparts [HHS Ref. No. E-074-2007/0-PCT-02];
35. U.S. Patent Application No. 12/528,796 filed August 26, 2009 [HHS Ref. No. E-074-2007/0-US-07]; Australia Patent Application No. 2008221383 filed February 27, 2008 [HHS Ref. No. E-074-2007/0-AU-03]; Europe Patent Application No. 08743578.0 filed February 27, 2008 [HHS Ref. No. E-074-2007/0-EP-05]; Canada Patent Application No. 2,678,404 filed February 27, 2008 [HHS Ref. No. E-074-2007/0-CA-04]; Japan Patent Application No. not yet assigned filed February 27,

2008 [HHS Ref. No. E-074-2007/0-JP-06] as well as all continuation, divisional and pending foreign counterpart applications.

Group II—Nonexclusive Licensed Patent Rights

1. U.S. Patent Application No. 60/111,582 filed December 9, 1998 as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-256-1998/0-US-01];
2. PCT Patent Application No. PCT/US1999/26866 filed November 12, 1999 as well all issued and pending foreign counterparts [HHS Ref. No. E-256-1998/0-PCT-02];
3. U.S. Patent No. 6,969,609 issued November 29, 2005; U.S. Patent No. 7,211,432 issued May 1, 2007; U.S. Patent Application No. 11/723,666 filed March 21, 2007; as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-256-1998/0, 1];
4. U.S. Patent Application No. 60/448,591 filed February 20, 2003 as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-028-2007/0-US-01];
5. PCT Patent Application No. PCT/US2004/005077 filed February 20, 2004 as well all issued and pending foreign counterparts [HHS Ref. No. E-028-2007/0-PCT-02];
6. U.S. Patent Application Nos. 60/448,591 and 10/543,944 filed February 20, 2003 and February 20, 2004 respectively, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-028-2007/0];
7. PCT Patent Application No. PCT/US1998/003032 filed September 2, 1998 as well all issued and pending foreign counterparts [HHS Ref. No. E-134-2007/0-PCT-02];
8. U.S. Patent No. 6,699,475 issued March 2, 2004, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-134-2007/0];

9. PCT Patent Application No. PCT/US1989/03701 filed August 25, 1989 as well all issued and pending foreign counterparts [HHS Ref. No. E-135-2007/0-PCT-02];
10. U.S. Patent No. 5,093,258 issued March 3, 1992, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-135-2007/0];
11. PCT Patent Application No. PCT/US1989/02486 filed June 7, 1989 as well all issued and pending foreign counterparts [HHS Ref. No. E-136-2007/0-PCT-02];
12. U.S. Patent Application No. 07/205,189 filed June 10, 1988, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-136-2007];
13. U.S. Patent Application No. 60/625,321 filed November 5, 2004 as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-138-2007/0-US-01];
14. PCT Patent Application No. PCT/US2005/040170 filed November 4, 2005 as well all issued and pending foreign counterparts [HHS Ref. No. E-138-2007/0-PCT-02];
15. U.S. Patent Application No. 60/625,321 filed November 5, 2004, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-138-2007];
16. U.S. Patent Application No. 60/678,329 filed May 5, 2005 as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-139-2007/0-US-01];
17. PCT Patent Application No. PCT/US2006/017765 filed May 5, 2006 as well all issued and pending foreign counterparts [HHS Ref. No. E-139-2007/0-PCT-02];
18. U.S. Patent Application No. 60/678,329 filed May 5, 2005, as well as all continuation and divisional applications, and issued and pending foreign counterparts [HHS Ref. No. E-139-2007/0]; and

The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for development of therapeutics for human colorectal cancer in all geographic territories.” For the avoidance of doubt, delivery formulations shall specifically exclude canary poxvirus vectors, NYVAC, non-viral eukaryotic expression vectors and recombinant yeast vectors.”

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

FOR FURTHER INFORMATION: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Sabarni K. Chatterjee, Ph.D., M.B.A. Licensing and Patenting Manager, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5587; Facsimile: (301) 435-4013; E-mail: chatterjeesa@od.nih.gov.

SUPPLEMENTARY INFORMATION: Cancer immunotherapy is a recent approach where tumor associated antigens (TAAs), which are primarily expressed in human tumor cells, and not expressed or minimally expressed in normal tissues, are employed to generate a tumor-specific immune response. Specifically, these antigens serve as targets for the host immune system and elicit responses that results in tumor destruction.

The initiation of an effective T-cell immune response to antigens requires two signals. The first one is antigen-specific via the peptide/ major histocompatibility complex and the second

or “costimulatory” signal is required for cytokine production, proliferation, and other aspects of T-cell activation.

The patents and patent applications describe a vaccine technology, TRICOM, in conjunction with tumor associated antigens (TAAs). The TRICOM technology employs avirulent poxviruses to present a combination of costimulatory signaling molecules with tumor-associated antigens (TAAs) to activate T-cells and break the immune systems tolerance towards cancer cells. This is achieved using recombinant poxvirus DNA vectors that encode both T-cell costimulatory molecules and TAAs. The combination of the three (3) costimulatory molecules B7.1, ICAM-1 and LFA-3, hence the name TRICOM, has been shown to have more than the additive effect of each costimulatory molecule when used individually to optimally activate both CD4+ and CD8+ T cells. When a TRICOM based vaccine expressing TAAs is administered it greatly enhances the immune response against the malignant cells expressing those TAAs. The addition of the two well-known TAAs, carcinoembryonic antigen (CEA) and MUC-1 to the TRICOM vector results in the PANVAC vaccine, which is used in a prime and boost vaccine strategy. It is well established that the over-expression of these two (2) TAAs are associated with the presence of a variety of carcinomas; including colorectal cancer and therefore PANVAC can potentially be an effective cancer vaccine for colorectal cancer. . Additionally, new tumor associated antigens can also be used with TRICOM to develop novel vaccines. For example, Brachyury, well known for its role in developmental cell biology and recently been implicated in tumor cell invasion and metastasis, has been shown to be aberrantly expressed in several tumors including colorectal tumors. As a result, Brachyury is being used as a tumor associated antigen along with TRICOM and has potential as a cancer immunotherapeutic vaccine for the treatment of several tumors including colorectal cancer.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives

written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

May 23, 2012
Date

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National Institutes of Health

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